

**Remarks**

Upon entry of this amendment, claims 1-8, 10-15, and 18-19 will be pending. Claims 2-5, and 11-15 have been amended herein and new claims 18 and 19 have been added. Support for the amendment to claim 14 can be found in originally filed claims 1, 10 and 11. Support for new claim 18 can be found in originally filed claim 12. Support for new claim 19 can be found in originally filed claim 15. No new matter has been added.

***The § 101 rejections***

Claims 1-8 and 10-15 have been rejected under 35 U.S.C. § 101 for lack of utility. The Examiner has stated that Applicants previously submitted arguments and the Declaration of Dr. Patturajan ("the Patturajan Declaration") were insufficient to overcome the rejection of claim 1-8 and 10-15. The Examiner alleges that "the instant specification, as filed fails to present any support regarding the specificity of the instant SEC1/FGF and activation of the FGF receptor b2. At the time of the invention, the information about receptor specificity of SEC1/FGF was not available." (*See* pages 4-5 of the Office Action). Because the Examiner has not accepted the Patturajan Declaration, Applicants traverse.

Applicants are permitted to submit after filing evidence showing utility as long as there is an appropriate nexus to the subject matter of the specification. MPEP 2107 states:

(3) If the applicant has not asserted any specific and substantial utility...[t]he 35 U.S.C. 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:

(i) Explicitly identify a specific and substantial utility for the claimed invention; and

(ii) Provide *evidence* that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. The *examiner should review any subsequently submitted evidence of utility using the criteria outlined above*. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention. (Emphasis added).

The Patturajan Declaration has a nexus with the subject matter of the specification. The present application describes the linkage of the fibroblast growth factors (FGFs) with their cognate high affinity receptors (FGFRs) and the importance of FGF-FGFR interactions in cell survival, replication, differentiation, adhesion, and motility, through effects on gene expression and the cytoskeleton. (*See* instant specification at page 9, lines 3-21). The Patturajan Declaration contains Exhibits A and B. Exhibit A discloses the stimulatory effect of the claimed polypeptide on cell proliferation (*See* Patturajan Declaration, ¶¶ 5-6). Exhibit B discloses the differential expression of SEC1/FGF in patients suffering from an inflammatory disorder (Crohn's Disease) and in tissue culture models of inflammation (*See* Patturajan Declaration, ¶¶ 7-9).

The Patturajan Declaration (*e.g.*, ¶¶ 5-6 and Exhibit A) provides additional support for the FGF-FGFR association. Therefore, Applicants assert that the data in the Patturajan Declaration has a probative relationship with the as filed specification, and the data in the Patturajan Declaration can (and should) be used to provide evidence that a specific and substantial asserted utility or a well established utility of the claimed protein existed at the time of filing. Moreover, the as filed specification discloses the importance of regulation of FGF signaling, and the association of FGFRs with human cancers and inflammatory disease, including chronic pancreatitis. (*See* instant specification at page 9, lines 16-21). The Patturajan Declaration (*e.g.*, ¶¶ 7-9 and Exhibit B) provides additional support for the role of SEC1/FGF as a mediator of inflammatory disorders. Therefore, Applicants assert that the data in Exhibit B of the Patturajan Declaration also has a probative relationship with the as filed specification, and should be used to provide evidence that a specific and substantial asserted utility or a well established utility of the claimed protein existed at the time of filing. The utility of SEC1/FGF of SEQ ID NO:2, demonstrated by the specification as filed the Patturajan Declaration, including Exhibits A and B, shows that SEC1/FGF is useful in regulating cell proliferation, a key event in control of normal physiological systems and in proliferative disorders. Moreover, SEC1/FGF's presence is useful in identifying proliferative cells, and cells with the capacity to proliferate (*e.g.*, FGFR-bearing cells). Additionally, SEC1/FGF is useful as a probe for inflammatory disorders, including psoriasis. (*See* Exhibit B).

Applicants submit that at least one substantial and specific utility exists for the claimed invention and is readily apparent based on the teachings of the specification and is further demonstrated by the Declaration of Dr. Patturajan. Therefore this rejection should be withdrawn.

***The 35 USC § 112, first paragraph rejections***

Claims 1-8 and 10-15 have been rejected under 35 U.S.C. § 112, first paragraph, for not providing a either a clear asserted utility or a well established utility for the polypeptide of SEQ ID NO:2. Arguments made above in reference to the rejection under 35 U.S.C. § 101 apply to this 35 U.S.C. § 112 rejection as well. If the above rejection is withdrawn, this rejection will also be withdrawn.

Claims 14 and 15 have been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement, the Examiner stating that claim 14, directed to a process for producing a polypeptide, depends from claim 1, which encompasses a compliment of a nucleic acid that encodes SEQ ID NO:2, and that the prior art does not teach how to produce a polypeptide by using a nucleic acid that is complementary to a nucleic acid encoding the polypeptide. Claim 15 has been rejected as dependent on claim 14.

In response, Applicants note that claim 14 has been amended herein to recite, in part, “a process for producing the polypeptide of SEQ ID NO: 2, said process comprising... providing the isolated cell of claim 11, wherein said isolated cell comprises a vector comprising an isolated nucleic acid comprising a nucleic acid sequence encoding the polypeptide of SEQ ID NO: 2...” Claim 14, as amended herein, is not drawn to the compliment of a nucleic acid encoding the polypeptide of SEQ ID NO: 2. Applicants assert that one of ordinary skill in the art would be able produce the polypeptide of SEQ ID NO:2 without undue experimentation, therefore, claim 14 is fully enabled by the as filed specification. Since claim 14, as amended herein, is enabled, claim 15, which depends from this claim, is also enabled. This rejection can be withdrawn.

***The 35 USC § 112, second paragraph rejection***

Claims 14 and 15 have been rejected under 35 U.S.C. § 112, second paragraph as indefinite for the recitation of the term “a polypeptide” in claim 14. Claim 15 has been rejected as dependent on claim 14.

In response, Applicants note that claim 14, as amended herein, is drawn to a "process for producing the polypeptide of SEQ ID NO: 2..." Since it is clear which polypeptide is intended by claim 14, the metes and bounds are determined by one of ordinary skill in the art. Thus, Applicants assert that claim 14, as amended herein, is definite. Since claim 14, as amended herein, is definite, claim 15, which depends from this claim, is also definite. This rejection can be withdrawn.

### ***The 35 USC § 102 rejections***

Claims 1-8 have been rejected under 35 USC § 102(a) as being anticipated by WO 01/18228. The Examiner states that because the instant application does not meet the requirements of 35 USC § 112, first paragraph, it is not entitled to the claimed priority date of May 14, 1999. (See Office action, page 6).

Applicants traverse the Examiner's denial, and the assignment of October 31, 2001 as the effective filing date of the instant application. As discussed *supra*, Applicants assert that the instant application meets the requirement of 35 USC §§ 101 and 112, first paragraph. Therefore, the instant application is entitled to the benefit of the earlier filing date under 35 USC § 120. Thus, the instant application should be afforded the priority date of May 14, 1999, when determining patentability of the claims 1-8 over the cited WO 01/18228, in which case the rejection under 35 USC § 102(a) is inappropriate and should be withdrawn.

### ***Claim Objections***

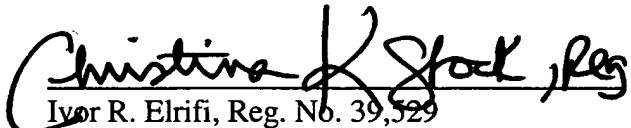
The Examiner has objected to claims 12 and 15 under 37 CFR §1.75(c) as being in improper form for failing to further limit the subject matter of a previous claim in their recitation of the phrase "a prokaryotic or eukaryotic cell." Claims 12 and 15 have been amended herein to delete the term prokaryotic. As such, claims 12 and 15, as amended herein, limit the subject of the claims upon which they depend. This objection should be withdrawn.

Appl. No. 09/998,966  
Amdt. dated March 1, 2004  
Reply to Final Office action of October 30, 2003

### CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

  
En Ivor R. Elrifi, Reg. No. 39,529 *Christina K. Stock, Reg. No. 45,899*  
Cynthia A. Kozakiewicz, Reg. No. 42,764  
Attorneys for Applicants  
c/o MINTZ, LEVIN  
Telephone: (617) 542-6000  
Facsimile: (617) 542-2241  
Customer No.: 30623

Dated: March 1, 2004

TRA 1891501v1